

1 REMARKS

2 Status of the Claims

3 Claims 1, 7-23, 26, 27, 52, 54-57 and 59 are pending in the present application, Claims 2, 3, 6,
4 and 28-51 having been previously canceled, and Claims 4, 5, 24, 25, 53, and 58 having been canceled
5 herein, and new Claim 59 having been added herein. Claims 1, 21, 22, 23, 52, 53, 54, and 57 have been
6 amended to more clearly define the subject matter being claimed.

7 Brief Summary of Telephone Interview

8 On December 1, 2009, applicants' attorney (Michael C. King, Registration No. 44,832) conducted
9 a telephone interview to discuss the Office Action with Examiner Utama and Primary Examiner Mosser.
10 Before the interview, an agenda discussing aspects of the references cited and a proposed amendment
11 were sent to Examiner Utama. During the telephone interview, each independent claim was discussed.

12 It was generally agreed that independent Claim 1 distinguished over the cited art.

13 It was generally agreed that the means plus function clauses in independent Claims 53 and 60
14 needed to be revised.

15 It was generally agreed that adding language such as follows to the remaining independent claims
16 would enable the remaining claims to clearly distinguish over the cited art: *a simulated patent skull suture*
17 *comprising a first material, a simulated fused skull suture comprising a second material, an echogenicity*
18 *of the first material being substantially lower than an echogenicity of the second material.* Similarly, it
19 could be recited that *an echogenicity of the second material being substantially higher than an*
20 *echogenicity of the first material.*

21 Applicants' attorney would like to thank Examiner Utama and Primary Examiner Mosser for their
22 time and willingness to discuss these issues during the Telephone Interview.

23 Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

24 The Examiner has rejected Claims 21-26 and 58 as being indefinite because the Examiner
25 believes that the filler material is not part of the claimed invention. Claim 21 has been amended to more
26 positively recite the element to which the Examiner objects. Claim 58 has been canceled. The rejection
27 under 35 U.S.C. § 112 should be withdrawn.

28 The Echogenicity of Materials Disclosed in the Prior Art

29 Several of the pending claims recite first and second materials whose echogenicity are
30 substantially different, such that the first and second materials can be readily distinguished in an

1 ultrasound image. These claims have been repeatedly rejected under the rationale that the materials
2 disclosed by Gain are different, and therefore ***must have*** echogenicities that are sufficiently different such
3 that the first and second materials can be readily distinguished in an ultrasound image.

4 Applicants respectfully object to the assumption that because the materials disclosed by Gain are
5 different, those materials must be readily distinguishable in an ultrasound image. There simply is no
6 evidence to support the assumption that the echogenicities of the materials disclosed by Gain are
7 sufficiently different to enable those materials to be distinguished in an ultrasound image. Despite
8 applicants' traversing this rejection, no evidentiary support of that assumption has been provided.

9 Gain discloses specific materials. If those materials can indeed be readily distinguished from one
10 another in an ultrasound image, then evidence to that effect must be provided to support a *prima facie*
11 rejection. However, none of the cited art discloses whether or not the different materials disclosed by
12 Gain can be readily distinguished from one another in an ultrasound image.

13 Applicants are not disputing that *some* different materials can have sufficiently different
14 echogenicities to enable those materials to be distinguished in ultrasound images. Applicants are simply
15 pointing out that without *any* evidence about the echogenicities of the materials disclosed by Gain, it is
16 improper to assume that those materials can be distinguished in an ultrasound image.

17 It has been asserted that the epoxy resin used to form Gain's cranium and the silicone elastomers
18 used to form Gain's soft parts have different densities, and thus must have different echogenicities. No
19 evidence has been provided as the relative densities of those materials, but even if their densities are not
20 identical, no evidence has been presented showing that their densities result in echogenicities that are
21 sufficiently different for the materials to be distinguishable in an ultrasound image. Again, *no evidence*
22 *has been provided that the epoxy resin used to form the cranium and the silicone elastomers used to form*
23 *the soft parts can be readily distinguished in an ultrasound image.*

24 Applicants' own disclosure provides empirical evidence of the echogenicities of three different
25 materials, each of which presumably have different densities. Two of those materials, solid plastic and a
26 malleable polymeric mixture, have echogenicities that are so similar that they cannot be readily
27 distinguished in an ultrasound image, even though the materials are different. *This empirical finding*
28 *absolutely contradicts the assertion that if materials are different they can be distinguished in an*
29 *ultrasound image.* A third material, a starch/glue mixture, has an echogenicity that is substantially
30

1 different than the first two materials, such that the starch/glue mixture can be readily distinguished from
2 the plastic and malleable polymer in an ultrasound image.

3 Applicants' specification clearly discloses an empirical model that was imaged using ultrasound
4 (FIGURE 5C is an ultrasound image of the model). The empirical model was made using a plastic doll's
5 head (page 10, lines 3 and 4). Openings about 1 mm wide were made at anatomically correct locations
6 for skull sutures (page 10, lines 4 and 5, and page 18, line 4). Openings intended to simulate a patent
7 skull suture were filled with a starch/glue mixture (page 10, lines 5-12). Openings intended to simulate a
8 fused skull suture were filled a malleable polymer (page 14, lines 12-25). The model was used by
9 radiology residents and fellows, who were able to successfully distinguish the patent and fused sutures
10 due the echogenicity difference between the different materials (page 20, lines 12-21).

11 Significantly, applicants empirically determined that the specified malleable polymer (page 14,
12 lines 12-25) filling an opening in a hard plastic doll's head could not be readily distinguished from the
13 hard plastic doll's head, while the starch/glue mixture (page 10, lines 5-12) could be readily distinguished
14 from both the plastic doll's head and the specified malleable polymer filling an opening in the doll's head,
15 as shown in FIGURE 5C.

16 Note that applicants have shown that two different materials (a plastic doll's head and a malleable
17 polymer) can be difficult to distinguish in an ultrasound image. In contrast, the cited art provides no
18 evidence as to whether or not the different materials disclosed by Gain can or cannot be readily
19 distinguished in an ultrasound image, and because of that lack of evidence, a *prima facie* rejection cannot
20 be supported.

21 It is also interesting to note that the materials disclosed by Gain are more like the hard plastic
22 doll's head and the malleable polymer disclosed by applicants than a starch/glue mixture, which strongly
23 suggests that the materials disclosed by Gain would be difficult to distinguish in an ultrasound image.
24 Gain discloses a cranium made from epoxy resin (column 2, line 60; column 5, line 55). Such a material
25 is similar to the plastic used for doll's heads. Gain discloses that soft parts are made using a silicone
26 elastomer (column 11, lines 16-56). The specific malleable polymer (whose echogenicity closely matches
27 the hard plastic doll's head) disclosed by applicants is a silicone elastomer (65%).

28 Applicants respectfully submit that it is illogical to on one hand can assert (without any supporting
29 evidence) that a rigid cranium made from cured epoxy resin can be distinguished from soft parts made
30 from a silicone elastomer in an ultrasound image, and at the same time disregard evidence from

1 applicants' specification that a plastic doll's head cannot be readily distinguished from a silicone
2 elastomer in an ultrasound image.

3 Claims Rejected Under 35 U.S.C. § 103(a)

4 Claims 1, 4-5, 7-13, 15, 18-20, 22, and 27 have been rejected under 35 U.S.C. § 103(a) as being
5 unpatentable over U.S. Patent No. 4,708,836 (Gain et al. - hereinafter referred to as "Gain") in view of
6 NPL #1, "Infant Skull Model and Sculpted Head" (retrieved on June 09, 2002).

7 Claims 14, 16, 17, 21-26 and 52-58 have been rejected under 35 U.S.C. § 103(a) as being
8 unpatentable over Gain in view of NPL #1, in view of U.S. Patent No. 5,609,485 (Bergman et al.) and
9 further in view of Bergman (U.S. Patent No. 5,609,485).

10 Claims 4, 5, 24, 25, 53 and 58 have been canceled herein.

11 In the interest of reducing the complexity of the issues for the Examiner to consider in this
12 response, the following discussion focuses on independent Claims 1, 21, 27, 52, 54, and 57. The
13 patentability of each remaining dependent claim is not necessarily separately addressed in detail.
14 However, applicants' decision not to discuss the differences between the cited art and each dependent
15 claim should not be considered as an admission that applicants concur with the Examiner's conclusion
16 that these dependent claims are not patentable over the disclosure in the cited references. Similarly,
17 applicants' decision not to discuss differences between the prior art and every claim element, or every
18 comment made by the Examiner, should not be considered as an admission that applicants concur with
19 the Examiner's interpretation and assertions regarding those claims. Indeed, applicants believe that all of
20 the dependent claims patentably distinguish over the references cited. In any event, a specific traverse of
21 the rejection of each dependent claim is not required, since dependent claims are patentable for at least the
22 same reasons as the independent claims from which the dependent claims ultimately depend.

23 Patentability of Independent Claim 1

24 Claim 1 has been amended to now recite *A medical simulator for training ultrasound operators to*
25 *perform craniosynostosis screenings using medical ultrasound, comprising a substantially life size model*
26 *of a human infant head, a skull portion of the model being primarily fabricated from a first material, said*
27 *skull portion including at least one simulated patent skull suture comprising a second material, **the***
28 ***second material having an echogenicity substantially lower than an echogenicity of said first material,***
29 *such that each simulated patent skull suture can be readily distinguished in an ultrasound image of said*
30 *model, with portions of the model corresponding to the first material appearing relatively brighter and*

1 portions of the model corresponding to the second material appearing relatively darker in the ultrasound
2 image, ***an interior volume of the model being substantially empty*** (emphasis added).

3 Significantly, Gain's head does not include a substantially empty interior volume. The voids
4 initially present in the synthetic cranium are filled with simulated soft tissue, such as simulated brains and
5 eyes. Those soft tissues are critical to Gain's model, as they are present to enable Gain's model to be used
6 in automotive crash tests to understand how impact forces affect the various parts of the human head.
7 Thus, modifying Gain to achieve a model having a substantially empty interior volume would render
8 Gain ***unsatisfactory for its intended purpose*** (see MPEP 2143.01). Without the soft tissues such as the
9 brain and eyes in the interior volume of Gain's model, accurate crash test studies could not be conducted.

10 The specification provides support for this amendment in the paragraph beginning at line 18 on
11 page 18. That paragraph discusses three embodiments, a hollow head with no backing support for the fill
12 material (functional if the fill material is sufficiently tacky), a hollow head with limited backing support
13 for the fill material (a relatively thin layer of backing material, such as duct tape), and a hollow head filled
14 with a hypoechoic material. Claim 1, as amended, reads on the first two of these embodiments.

15 Since dependent claims inherently include all of the recitation of the independent claims from
16 which they ultimately depend, for at least the same reasons as noted above in connection with
17 independent Claim 1, the rejection of dependent Claims 7-13, 15, and 18-20, should also be withdrawn.

18 Comments Applicable to Bergman

19 The Examiner has asserted that Bergman teaches embedding a transmitter in a mannequin, and
20 that the transmitter can be embedded in different parts of the mannequin. The Examiner has asserted that
21 such disclosure is equivalent to *selectively modifying a model between training sessions by enabling a*
22 *filler material to be added to an opening.*

23 Applicants respectfully submit that the Examiner is taking elements disclosed by Bergman out of
24 context. Bergman simply does not teach that the transmitter is moved to reconfigure the simulator.
25 Bergman simply teaches that the specific location of the transmitter is not critical. There is no disclosure
26 in Bergman teaching or suggesting that the location of the transmitter is ***changed*** once it has been placed
27 in or on the mannequin. Bergman literally states: *Then a transmitter 34 can be embedded in the body at*
28 *any of a plurality of desired locations, or it can be attached outside of the body at any of a plurality of*
29 *locations.* That simply does not teach or suggest moving the transmitter once it has been placed to
30

1 reconfigure the simulator, to change a simulated patent skull suture to a simulated fused skull suture, or to
2 reconfigure the simulator in any other fashion.

3 Indeed, there is no need to move the transmitter, because as long as the range of the transmitter is
4 sufficiently large, and the transmitter in/on the mannequin and the sensor in the simulated ultrasound
5 imaging probe can communicate, the location of the transmitter is irrelevant (which is why Bergman
6 discloses that the transmitter can be located anywhere in or on the mannequin). The function of the
7 transmitter is to enable the relative location of the sensor in the simulated ultrasound imaging probe to be
8 determined relative to the mannequin, such that as simulated ultrasound imaging probe is moved relative
9 to the mannequin, simulated ultrasound unit 40 can determine the appropriate previously recorded
10 ultrasound images to display. That requires the relative positions of the transmitter and the model to be
11 known. If the transmitter is moved as suggested by the Examiner, then simulated ultrasound unit 40 will
12 no longer be able to provide the correct images, until the new information about the relative positions of
13 the transmitter and the mannequin are provided to simulated ultrasound unit 40. Moving the transmitter
14 would require simulated ultrasound unit 40 to be reprogrammed to relate the new position of the
15 transmitter relative to the mannequin. That requires additional effort, for no apparent benefit. A
16 modification to a reference that provides no benefit, and instead increases complexity and cost, does not
17 support a *prima facie* rejection.

18 Furthermore, the Examiner's assertion that Bergman's system is reconfigurable because the
19 transmitter can be moved is not well reasoned. As noted above, as long as the sensor/transmitter can
20 interact as desired, moving the transmitter provides no benefit. If there was a desire to change the
21 ultrasound image being displayed from an image of a patent skull suture to a fused skull suture, that
22 change could be accomplished by manipulating simulated ultrasound unit 40 (i.e., the processor that
23 retrieves previously recorded ultrasound images), without moving the transmitter. For example, assume
24 the simulated ultrasound imaging probe (which includes the sensor) is disposed at the anatomically
25 correct position to acquire an ultrasound image of a skull suture. So long as the transmitter is in range of
26 the sensor (and Bergman clearly suggests that the transmitter will be in range of the sensor regardless of
27 where the transmitter is physically located on/in the mannequin), the position of the transmitter is
28 irrelevant. The position of the transmitter relative to the mannequin is known, the transmitter determines
29 the position of the sensor relative to the mannequin, and simulated ultrasound unit 40 displays an image
30 of either a patent skull suture or a fused skull suture, depending on how simulated ultrasound unit 40 is

1 programmed (i.e., depending upon the previously acquired ultrasound images that are available for
2 display). If an ultrasound image of a fused skull suture is initially displayed, and one wishes to have an
3 ultrasound image of a patent skull suture displayed, then all that is required is for simulated ultrasound
4 unit 40 to access a different one of the prerecorded ultrasound images (this requires that ultrasound
5 images of both patent and fused skull sutures were previously acquired). No change in the position of the
6 sensor or transmitter is required. In fact, the Examiner notes that Bergman enables different pathologies
7 to be visualized by referring to column 2, line 15. An understanding of Bergman's operating principles
8 makes it clear that the pathology being displayed is a function of the programming of simulated
9 ultrasound unit 40 and the location of the simulated ultrasound imaging probe including the sensor, not a
10 function of the location of the transmitter.

11 With respect to the Examiner's comments regarding intended use applications, the claims have
12 been amended to positively recite structures that differ from the prior art.

13 Patentability of Independent Claim 21

14 Claim 21 has been amended to now recites:

15 *A reconfigurable medical simulator adapted to be used to train ultrasound operators to perform*
16 *craniosynostosis screenings using medical ultrasound, comprising:*

17 (a) *a substantially life size model of a human infant head, said model including a*
18 *plurality of skull suture openings disposed at locations corresponding to a skull suture;*

19 (b) *a quantity of a removable first material having an echogenicity such that when the*
20 *first material is disposed within an opening in the model corresponding to a skull suture, that opening*
21 *will appear as a patent skull suture in an ultrasound image of the model, the first material comprising a*
22 *solid or semi-solid hypoechoic material; and*

23 (c) *a quantity of a removable second material having an echogenicity such that when*
24 *the second material is disposed within an opening in the model corresponding to a skull suture, that*
25 *opening will appear as a fused skull suture in an ultrasound image of the model, the second material*
26 *comprising a solid or semi-solid echogenic material, **the second material having an echogenicity that is***
27 ***substantially higher than an echogenicity of the first material,** the first and second materials enabling a*
28 *user to selectively reconfigure the model by controlling which of the first and second materials are used*
29 *to fill specific openings, such that if an opening is filled the first material to simulate a patent skull suture*
30 *and the user desires that opening to appear as a fused skull in an ultrasound image of the model, the user*

1 *removes the first material and fills the opening with the second material, such that the opening will*
2 *appear as a fused skull suture in an ultrasound image of the model, there being a substantial difference in*
3 *the echogenicities of the first and second materials, such that the first and second materials are readily*
4 *distinguishable in an ultrasound image, the first and second materials being elements of the*
5 *reconfigurable medical simulator.*

6 Thus, Claim 21 recites a model head including a plurality of skull suture openings, and two
7 different fill materials that a user can insert into the skull suture openings. The solid/semisolid fill
8 materials are positively recited as part of the model, albeit it is up to a user to determine which openings
9 get which fill material. The first fill material has an echogenicity that makes a skull suture opening filled
10 with the first material appear as a patent skull suture. The second fill material has an echogenicity that
11 makes a skull suture opening filled with the second material appear as a fused skull suture. As agreed in
12 the above noted telephone interview, Claim 21 recites that the second material (which simulates a fused
13 skull suture) has an echogenicity that is substantially higher than an echogenicity of the first material
14 (which simulates a patent skull suture). This is similar to the language in Claim 1, which recites that the
15 first material (which simulates a patent skull suture) has an echogenicity that is substantially lower than an
16 echogenicity of the second material (which simulates a fused skull suture).

17 It has been previously argued that Bergman discloses a fill material (i.e., a transmitter) used to
18 change the echogenicity of an opening in a training model. As discussed in detail above, Bergman
19 discloses a transmitter that can be detected by a sensor that simulates an ultrasound imaging probe. The
20 transmitter can be placed just about anywhere one desires, but moving the transmitter requires
21 reprogramming the simulated ultrasound unit, such that the simulated ultrasound unit can determine
22 which previously recorded images to display based on the known location of the transmitter.

23 Bergman's system is reconfigurable, because different prerecorded ultrasound images can be
24 used, not because the transmitter location affects the image displayed. Actually, moving the transmitter
25 from its initial position would change the images being displayed, if the ultrasound imaging machine were
26 not reprogrammed to track the transmitter's position, as the movement of the transmitter would change
27 how the system tracks the relative position of the simulated ultrasound imaging probe. In other words, if
28 you move the transmitter and reprogram the simulated ultrasound imaging machine, there is no change in
29 the images displayed. If you move the transmitter and don't reprogram the simulated ultrasound imaging
30 machine, there is a change in the images displayed, because the system is no longer correctly tracking the

1 relative position of the simulated ultrasound imagining probe (i.e., the probe might be positioned to
2 acquire an image of the abdomen, but the system displays an ultrasound image of the leg).

3 Bergman simply does not teach or suggest that moving the location of the transmitter changes the
4 image to be displayed. Bergman most definitely does not teach or suggest that putting the transmitter in
5 an opening simulating a skull suture would change the previously recorded ultrasound image being
6 displayed from a patent skull suture to a fused skull suture.

7 With respect to the recited fill materials, the recited first fill material **must** (when inserted into a
8 skull suture opening and an ultrasound image of that opening is acquired) have an echogenicity that
9 causes the opening to appear in the ultrasound image as a patent skull suture. The recited second fill
10 material **must** (when inserted into a skull suture opening and an ultrasound image of that opening is
11 acquired) have an echogenicity that causes the opening to appear in the ultrasound image as a fused skull
12 suture. Even if Bergman's transmitter was small enough to be inserted in an opening in Gain's model
13 simulating a skull sutures, you might be able to see the transmitter itself in the ultrasound images. But
14 applicants do not understand how it can be argued that the transmitter would look like either a fused or a
15 patent skull suture. The claim requires that the first and second material actually look like real patent or
16 fused skull sutures in an ultrasound image. No evidence has been submitted as to the echogenicity of
17 Bergman's transmitters, thus there is no basis for asserting that a transmitter would appear as either a
18 patent or fused skull suture in an ultrasound image. Finally, Bergman's transmitters cannot logically be
19 equivalent to **both** the first and second materials, and none of the other cited art discloses materials that
20 are moveable from one opening to the next. The cited art simply does not teach or suggest a model with a
21 plurality of skull suture openings, and two different fill materials of substantially different echogenicities,
22 that can be used to selectively fill the skull suture openings.

23 Since dependent claims inherently include all of the recitation of the independent claims from
24 which they ultimately depend, for at least the same reasons as noted above in connection with
25 independent Claim 21, the rejection of dependent Claims 22, 23, and 26 should also be withdrawn.

26 Patentability of Independent Claim 27

27 As currently amended, Claim 27 recites that the patent and fused skull sutures are replaceable and
28 interchangeable, *such that a user can change the relative locations of each replaceable simulated patent*
29 *skull suture and each replaceable simulated fused skull suture to reconfigure the ultrasound trainer.*
30

1 As agreed in the above noted telephone interview, Claim 27 also recites that the first material
2 (which simulates each patent skull suture) has an echogenicity that is substantially lower than an
3 echogenicity of the second material (which simulates each fused skull suture).

4 Further, it must be recognized that the simulator of Claim 27 is configured to simulate a fused
5 skull suture in a non obvious manner, which is not taught or suggest in the cited art.

6 Anatomically speaking, a fused skull suture represents a joint between adjacent boney skull
7 plates, with little or no gap at the joint. A patent skull suture represents a joint between adjacent boney
8 skull plates, with a definite gap between the plates, the gap being filled with tissue. Gain includes a
9 realistic adult cranium, including fused skull sutures implemented by a mass of epoxy resin without an
10 opening or gap. The cranium proximate the patent skull sutures is cast as a single mass (it appears as if
11 the jaw is a separate casting). The simulator of Claim 27 simulates a fused skull suture by 1) having an
12 opening at the fused skull suture, and 2) filling that opening with a filler material that will simulate a fused
13 skull suture. The cited art simply does not teach or suggest a fused skull suture comprising an opening
14 filled with a echogenic material. Based on the disclosure of Gain and NPL#1, only patent skull sutures
15 would be formed using an opening and a fill material.

16 Thus, it should be apparent that Claim 27 is novel and non-obvious in view of the art cited. For
17 this reason, the rejection of independent Claim 27 under 35 U.S.C. § 103(a) should be withdrawn because
18 the cited art does not teach or suggest all of the recitation of Claim 27.

19 Patentability of Independent Claim 52

20 Claim 52 as amended recites:

21 *A reconfigurable medical simulator for training ultrasound operators to perform craniosynostosis*
22 *screenings using medical ultrasound, comprising a substantially life-size model of a human infant head,*
23 *said model including two eyes, a mouth, two ears, and a plurality of openings, each opening simulating a*
24 *skull suture, at least one of the plurality of openings being filled with a removable first material to*
25 *simulate a patent skull suture, and at least one of the plurality of openings being filled with a removable*
26 *second material to simulate a fused skull suture, **an echogenicity of the removable first material being***
27 ***substantially lower than an echogenicity of the removable second material,** a difference in echogenicity*
28 *of the removable first material in each simulated patent skull suture and the removable second material in*
29 *each simulated fused skull suture enabling each simulated patent skull suture to be readily*
30 *distinguishable from non suture portions of the model and from each simulated fused suture in an*

1 *ultrasound image of said model, the removable first material and the removable second material being*
2 *interchangeable, such that a user can change the relative locations of each simulated patent skull suture*
3 *and each simulated fused skull suture to reconfigure the ultrasound trainer* (emphasis added).

4 As agreed in the above noted telephone interview, Claim 52 recites that the first material (which
5 simulates each patent skull suture) has an echogenicity that is substantially lower than an echogenicity of
6 the second material (which simulates each fused skull suture).

7 Claim 52 patentably distinguishes over the cited art for substantially the same reasons as Claim 21
8 and 27. Note Claim 52 positively recites the first and second materials, thus there appears no basis for an
9 indefiniteness rejection of this claim.

10 Patentability of Independent Claims 54 and 57

11 Claims 54 and 57 are rejected over a combination of Gain, the first NPL reference, Cecchi, and
12 Bergman.

13 As agreed in the above noted telephone interview, Claims 54 and 57 recite that the second
14 material (which simulates each patent skull suture) has an echogenicity that is substantially lower than an
15 echogenicity of the first material (which forms the skull), and that the third material (which simulates
16 each fused skull suture) has an echogenicity that is substantially higher than an echogenicity of the second
17 material (which simulates each patent skull suture).

18 As discussed above, Bergman 8:35-50 **does not** disclose the concepts of a third material filling an
19 opening as asserted in this rejection.

20 Furthermore, as noted above, Gain discloses that a simulated fused skull suture is fabricated by
21 casting a cranium without an opening at the area corresponding the fused skull suture. The simulator of
22 Claims 54 and 57 simulate a fused skull suture by 1) having an opening at the fused skull suture, and 2)
23 filling that opening with a filler material that will simulate a fused skull suture. The cited art simply does
24 not teach or suggest a fused skull suture comprising an opening filled with a echogenic material. Based
25 on the disclosure of Gain and NPL#1, only patent skull sutures would be formed using an opening and a
26 fill material.

27 Accordingly, the rejection of independent Claims 54 and 57 under 35 U.S.C. § 103(a) should be
28 withdrawn because the cited art does not teach or suggest all of the recitation of Claims 54 and 57.

1 Since dependent claims inherently include all of the recitation of the independent claims from
2 which they ultimately depend, for at least the same reasons as noted above in connection with
3 independent Claim 54, the rejection of dependent Claims 55 and 56 should also be withdrawn.

4 Patentability of Independent Claim 59

5 Claim 59 is similar to Claim 21, but recites that the first fill material comprises starch and glue
6 mixture, and the second fill material comprises a silicone elastomer.

7 Claim 59 specifically recites that the second material (the silicone elastomer to simulate the fused
8 skull suture) is substantially more echogenic than the first material (the starch/glue mixture to simulate the
9 patent skull suture).

10 The starch and glue fill material distinguishes over the cited art. There simply has been no
11 evidence presented of fabricating any structure at all out of a starch/glue mixture to control the appearance
12 of a structure in an ultrasound image.

13 Conclusion

14 Upon consideration of the amendment to the claims and the Remarks set forth above, applicants
15 respectfully request that the Examiner telephone them to discuss additional amendments, if the
16 amendments have not addressed the Examiner's concerns with respect to 35 U.S.C. § 112.

17
18 Respectfully submitted,

19
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23 MCK/RMA:elm
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